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Attorney's Docket No. 048057/275988 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/060,697	Confirmation No.: 8553
Applicant(s):	Petersen *et al.*	
Filed:	January 30, 2002	
Art Unit:	1651	
Examiner:	Witz, Jean C.	
Title:	BONE GRAFT SUBSTITUTE COMPOSITION	

Docket No.: 048057/275988
Customer No.: 00826

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR § 1.193

The following comments are offered in response to the Examiner's Answer mailed on June 28, 2005. Although Appellant has chosen to focus on a several key issues herein, this should not be construed as an abandonment of any arguments originally made in the Appeal Brief filed on April 11, 2005.

I. Comments on Examiner's Answer

First, Appellant reiterates that the teachings of O'Leary are manifestly inconsistent with the use of calcium sulfate hemihydrate, which is known in the art (as admitted by the Examiner) to result in a composition that hardens upon exposure to an aqueous liquid. The O'Leary reference is directed to a "flowable" composition and particularly states that the object of the O'Leary invention is to provide "a composition of liquid or pastelike consistency" and to apply "the composition" to a bone defect site to induce new bone growth (column 1, lines 36-43). The O'Leary disclosure also states that the bone powder composition described therein can be prepared beforehand and stored in a sterile condition for later use, and even stored within a syringe or other means for applying the composition (column 1, lines 63-67; column 4, lines 34-37)). Appellant respectfully submits that the Examiner has not adequately explained how one of ordinary skill in the art would be motivated to overlook this clear requirement in O'Leary by adding a substance known to cause hardening (i.e., negate flowability) of a composition.

In response, the Examiner begins by noting that an argument in favor of nonobviousness cannot be supported by attacking references individually. Appellant respectfully submits that the arguments presented herein and in the Appeal Brief do not constitute merely attacking references individually, but rather, represent a perfectly acceptable attempt to point out that the teachings of the combined references as a whole must be considered. In the present case, it is Appellant's opinion that the Examiner is ignoring important teachings of O'Leary that strongly weigh against a finding of motivation to combine the references in the manner required to support the rejection.

Appellant also takes issue with the Examiner's strained interpretation of the term "flowable" in O'Leary as only describing the condition of the composition "for the purpose of handling of the composition during application to the bone defect." The Examiner appears to allege that the term "flowable" would not be interpreted as a condition that is required to be maintained throughout the time period that the composition spends *in situ* at the site of the bone defect. The Examiner also points out that new bone growth is desired with the use of any bone graft composition and that, ultimately, the composition will be replaced by mineralized, and therefore hardened, bone tissue.

Appellant respectfully submits that there is no support in O'Leary for somehow confining the description of the O'Leary composition as "flowable" to a specific time period (i.e., only during handling and application). There is nothing in the O'Leary reference that suggests that the composition described therein is not intended to be "flowable" (i.e., having a consistency that is somewhere between runny and pastelike) after application to the bone defect. The Examiner even notes on page 19 of the Examiner's Answer that "a composition and its properties are not separable." Under this principle, the flowable composition of O'Leary would be expected to remain flowable *in situ* at the site of the bone defect as well as during handling and application. The fact that hardened bone tissue enters the bone defect site over time is irrelevant. The hardened bone tissue is not the O'Leary composition, but rather its replacement. The fact that the bone tissue is hardened has no impact on the properties of the bone powder composition of O'Leary. There is simply nothing in O'Leary to suggest that the composition described therein should be anything but flowable at any time period after it is prepared. Everything in O'Leary suggests that the compositions described therein are intended to have a flowable consistency. Thus, one of ordinary skill in the art would clearly not be motivated to alter the composition of

O'Leary by addition of an ingredient known to harden relatively quickly because it would be expected that the resulting composition would no longer meet the flowable limitation required in O'Leary.

The Examiner states that the terms "extended period of time" and "short period of time" are not found in the O'Leary patent and concludes that Appellant's arguments are therefore not germane to the rejection of record. However, the fact that the precise language used by Appellant in its brief does not appear in O'Leary is hardly evidence that Appellant's argument is irrelevant. As noted above, the O'Leary reference does suggest that the bone powder composition described therein can be prepared "beforehand" and "stored" in a sterile condition for "later" use. O'Leary also states that the composition can be prepared "well in advance." While not setting a numerical time period, these are obvious temporal terms that suggest that the composition will remain in a consistent state for an extended period of time. Otherwise, storage and later use would not be possible. For instance, one of ordinary skill in the art would not view an aqueous solution of calcium sulfate hemihydrate as suitable for preparation "beforehand" and storage for "later" use because mixing the composition "well in advance" of the time of its use would result in a hardened composition that could no longer be manipulated as desired at the time of application. It is also clear that one of ordinary skill in the art would not view a calcium sulfate hemihydrate solution as suitable for storage in the barrel of a syringe as suggested by O'Leary. Once a calcium sulfate hemihydrate composition hardens, it would not be expected to be flowable to the extent necessary to be used in a delivery device such as a syringe.

Additionally, Appellant respectfully disagrees with the Examiner's characterization of the prior art on page 12 of the Examiner's Answer. Therein, the Examiner alleges that the prior art indicates that "plasticizing substances such as are claimed are known to be used in prior art moldable bone graft compositions ***expressly for the purpose of improving the moldability*** of the composition" (emphasis added). Appellant respectfully submits that the art of record does not support this statement. The cellulose derivatives of O'Leary are used as thickeners to prevent settling. The Yim reference teaches that certain cellulose derivatives can be used as protein-sequestering agents. Obviously, neither of these stated uses is synonymous with improving moldability.

As noted in the Appeal Brief, the composition of the invention utilizes a plasticizing substance that retards the reaction of calcium sulfate hemihydrate with water, thereby increasing the amount of time required for the composition to harden, and which also improves the robustness of the composition, meaning the composition exhibits greater cohesiveness and improved handling characteristics. The Examiner has attempted to refute Applicants' assertion that the present invention represents the first discovery of these improved benefits by reference to a British patent. However, Appellant notes that the cited patent is not directed to bone graft substitute compositions as presently claimed. When Appellant referred to the prior art, the intent was to refer to art of relevance to the claimed field of the invention, which is bone graft substitute compositions. The British patent is directed to wall plasters and does not represent art that would be considered by one of ordinary skill in the field of bone graft substitute compositions. Presumably, this is why the Examiner is not relying on the British reference in any rejection of record.

Appellant also notes that the cases cited by the Examiner as relating to the obviousness of concentration ranges are irrelevant to the weight percent limitation of cancellous bone as presently claimed. The Wironen reference includes no range whatsoever for the concentration of cancellous bone. This is not a question of optimization within a range taught in the prior art reference because there is no range whatsoever in the prior art reference relied upon by the Examiner. Thus, there is nothing to provide the baseline from which one of ordinary skill in the art can optimize. The cited art is simply devoid of any concentration teaching for cancellous bone.

II. New Rejections

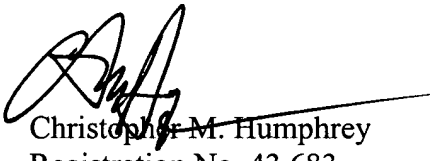
The Examiner's Answer includes three new rejections. Specifically, all pending claims are now rejected under the doctrine of obviousness-type double patenting as unpatentable over certain claims of U.S. Pat. No. 6,652,887, and provisionally rejected as obvious over certain claims of Appl. Nos. 09/947,833 and 09/327,761.

Appellant chooses to maintain the appeal despite the new grounds for rejection, but does not contest the new rejections at this time. Appellant reserves the right to address these

rejections at a later time, either through traversal, claim amendment, or by filing terminal disclaimers, upon the indication of otherwise allowable subject matter.

In light of the foregoing, and in addition to the arguments set forth in the Appeal Brief, Appellant again respectfully submits that the claims of record are patentable over the cited references. As a result, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the final rejection of the pending claims.

Respectfully submitted,



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